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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,145	07/03/2002	Nicole Zitzmann	080618-0241	6322

22428 7590 05/31/2007

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EXAMINER	
WILLIAMS, LEONARD M	

ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
05/31/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/031,145	ZITZMANN ET AL.	
	Examiner	Art Unit	
	Leonard M. Williams	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32,33 and 35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32,33 and 35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/5/2007 has been entered.

Response to Arguments

Applicant's arguments with respect to claims 32-33 and 35 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 32-33 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jacob et al. (WO99/24401), in view of Platt et al. (US Patent NO. 6462197) and Defoin et al. (6-Deoxy-Nojirimycin and 6-Deoxy-gulo-Nojirimycin in the racemic and D-series, D-Fuco-Nojirimycin and their 1-Deoxyderivatives via Hetero-Diels-Alder Cycloadditions, 1997, Tetrahedron, vol. 53, No. 40, pp. 13783-13796) and further in view of van den Broek et al. (Synthesis of oxygen-substituted N-alkyl 1-deoxynojirimycin derivatives: aza sugar a-glucosidase inhibitors showing antiviral (HIV-1) and immunosuppressive activity, Recl. Trav. Chim. Pays-bas, 1994, vol. 113, pp. 507-5166).

Jacob et al. teach, on pages 14-15, N-substituted-1,5-dideoxy-1,5-imino-D-glucose and galactose compounds of formula I wherein R is selected from C1-C20 alkyl groups containing 1-5 oxygen atoms (oxa derivatives) with preferred R oxa derivatives being 3-oxanonyl, 3-oxadecyl, 7-oxanonyl and 7-oxadecyl.

Jacob et al. does not teach N-nonyl-1,5,6-trideoxy-1,5-imino-D-galactitol nor N-(7-oxa-nonyl)-1,5,6-trideoxy-1,5-imino-D-galactitol compounds.

Platt et al. teach, in col. 1 lines 10-65, novel N-alkyl derivatives of deoxygalactonojirimycin (DGJ) in which the alkyl group is from 3-6 atoms. The inhibitory activity of these compounds have lead to their development as antihyperglycemic agents and anti-viral agents. DGJ has been shown to have better inhibitory activity compared to N-alkyl-deoxynojirimycin (DNJ).

DeFoin et al. teach, on pages 13783-13785, that aminosugars are rather unstable compounds and can be converted into their 1-deoxy derivatives which posses similar inhibitory activity properties. 1-deoxy-L-fuco-nojirimycin is described as a potent α-fucosidase inhibitor. L-fucose is equal to 6-deoxy-L-galactose thus 1-deoxy-L-fuco-nojirimycin is equivalent to 1,6-dideoxy-L-galacto-nojirimycin (or 1,5,6-trideoxy-L-galactonojirimycin). It is taught that 1,6-dideoxy-nojirimycin is known to posses inhibitory activity similar (though less effective) to 1-deoxy-nojirimycin. It is further taught that D-fuco-norjirimycin (equals 6-deoxy-D-galacto-nojirimycin) and 1,6-dideoxy-D-fuco-norjirimycin (equals 1,6-dideoxy-D-galacto-nojirimycin) can be readily synthesized.

van den Broek et al. teach, on page 508, that N-decyl-deoxynojirimycin is a potent α-glucosidase inhibitor in the HepG2 assay but showed significant toxicity. The toxicity was believed to be associated with the amphiphilicity of the molecule. In order to reduce the amphiphilicity of the compound either the N-decyl side chain's lipophilicity can be decreased or the aza-sugar ring can have its lipophilicity increased. The changing of the N-decyl group with N-(7-oxadecyl) was performed to reduce the side chains lipophilicity. It would also be possible to remove one or more of the hydroxyl groups on the aza-sugar in order to achieve an increased lipophilicity of the aza-sugar.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the 1,5-dideoxy and 1,5,6-trideoxy alditols with the D-galacto configuration of Platt et al. and DeFoin et al. in the Jacob et al. formula 1 compounds as the Jacob et al. compounds differ only in that they disclose only 1,5-dideoxy alditols. One would have been motivated to make such a change as van den Broek et al. demonstrate that changes in the aza-sugar portion of deoxynorjirimycin that would increase its lipophilicity would alter the toxicity profiles of the compounds. Removal of a hydroxyl group at the 6 position would result in an increase in the lipophilicity of the aza-sugar. Further Platt et al. demonstrated that the deoxygalactonojirimycin compounds demonstrated increased inhibition compared to deoxynojirimycin. One would expect a reasonable chance of success as DeFoin et al. details the synthesis of the 1,5,6-trideoxy D-galactitol compounds and Jacob et al. and Platt et al. demonstrate the introduction of alkyl moieties on the ring nitrogen. Further Jacob et al. details the synthesis of 1,5-dideoxy D-galactitol compounds the process of which could easily be

modified to utilize DeFoin et al. 1,5,6-trideoxy D-galactitol (equals 1,6-dideoxy-D-fuco) moieties.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leonard M. Williams whose telephone number is 571-272-0685. The examiner can normally be reached on MF 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

LMW

SHENGJUN WANG
PRIMARY EXAMINER